

APPLICANT(S): GLUKHOVSKY, Arkady  
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## **REMARKS**

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Applicant asserts that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

### **Status of Claims**

Claims 11-48 are now pending in the application.

Claims 21-34 and 36-46 have been withdrawn from consideration.

Claims 11-20 and 35 have been rejected.

Claims 11 and 35 have been amended in this submission. Applicant respectfully asserts that the amendments to the claims add no new matter.

Claims 47 and 48 have been newly added to further define inventions of the present application. Applicant respectfully asserts that the new claims add no new matter.

## **CLAIM REJECTIONS**

### **35 U.S.C. § 103 Rejections**

In the Office action, the Examiner rejected claims 11-20 under 35 U.S.C. § 103(a), as being unpatentable over Gross et al. (US Patent Application Publication No. 2004/0253304) in view of Iddan (US Patent Application Publication No. 2003/0214580). Applicants traverse the rejection for at least the reasons that follow.

As previously explained, the Gross reference is directed to drug delivery. The ingestible apparatus disclosed is intended solely for drug administration. The sole embodiment Applicant could locate in Gross' 60-page disclosure that involves an imaging device is the one referred by the Examiner, i.e., at para. [0075]. Thus, the embodiments associated with the camera embodiment have a driving mechanism for releasing the drug at a

location determined by on-board analysis of an image acquired by the camera. However, in order to find a detachable appendage, the Examiner points to an entirely different – and incompatible – embodiment in the Gross reference, i.e., para. [0367] and Fig. 15. The Gross reference, therefore, does not disclose an ingestible device having both a camera and a detachable appendage, as recited in claim 11.

Further, the Examiner concedes that Gross does not disclose a spherical housing to contain the imager, and cites the Iddan reference for disclosing interchangeability of the shapes of imaging capsules. The motivation suggested by the Examiner is that it would have been obvious to “construct the sheath of Gross in whatever shape is efficacious.” However, Applicants point out that the Examiner still has not specified why one of ordinary skill would have found a sphere to be efficacious. This is therefore an improper prima facie obviousness rejection. In response, the Examiner stated that it is beneficial to have round edges, and that no result of this combination would be unpredictable. Applicant disagrees. As previously explained, the combination of the spherical image and the detachable appendage, as claimed, unexpectedly result in permitting to image with the same capsule both narrow lumens (e.g., the esophagus) during a first part of the imaging process, and cavernous lumens (e.g., the roof of the stomach) during a second part of the imaging process.

In addition to the above, Applicant has amended claim 11 to recite that the housing comprises a “dome-shaped window through which a body lumen is illuminated and imaged,” and that the housing and detachable appendage “form an oblong capsule shape when joined together such that the dome-shaped window forms an end of the oblong capsule shape.” Preliminarily, it is respectfully noted that support for this amendment may be found throughout the application, including at Figure 3A of the specification, reproduced below:

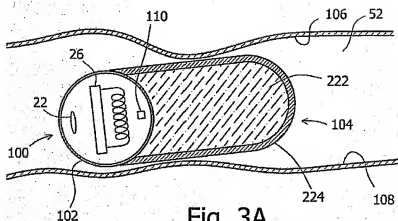
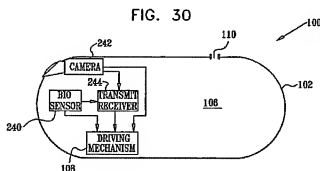


Fig. 3A

For the reasons below, this claimed structure is not disclosed, suggested, or rendered obvious by the Gross or Iddan references.

As discussed above, the Gross reference discloses one sole embodiment having a camera at Fig. 30:



However, this embodiment does not show either a “dome-shaped window through which a body lumen is illuminated and imaged,” or that the housing and detachable appendage “form an oblong capsule shape when joined together such that the dome-shaped window forms an end of the oblong capsule shape.”

With respect to the Iddan reference, the relevant portions relating to the imager and illumination unit are paragraph [0048], which explains Fig. 3 (reproduced below):

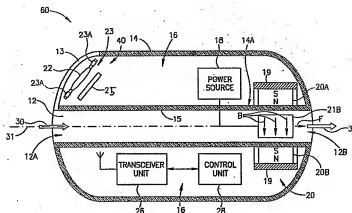


FIG. 3

[0048] The imaging device 60 may include some or all components of the transport device 50 of FIG. 1A and an imaging system 40. Other sensors or sensing systems, such as an ultrasonic sensing system, a pressure sensing system, etc., may be used. The imaging system 40 includes an optical system 22 and an imaging camera 25 (such as a CMOS camera, a CCD camera, or another suitable imaging device) and an illumination unit 23 including one or more of light sources 23A. The optical system 22, the imaging camera 25 and the illumination unit 23, may be constructed and operated as disclosed in detail for the optical system, the imaging camera and the illumination source, of U.S. Pat. No. 5,604,531 and/or PCT/IL01/00218 (International Publication Number WO 01/65995). However, other imaging systems may be used.

However, this embodiment of the Iddan reference does not disclose either a “dome-shaped window through which a body lumen is illuminated and imaged,” or that the housing and detachable appendage “form an oblong capsule shape when joined together such that the dome-shaped window forms an end of the oblong capsule shape.”

Accordingly, even if it would have been obvious to combine the teachings of the Gross and Iddan references, the combined device would not include a “dome-shaped window through which a body lumen is illuminated and imaged,” and that the housing and detachable appendage “form an oblong capsule shape when joined together such that the dome-shaped window forms an end of the oblong capsule shape.”

Therefore, claim 11, and claims 12-20, which depend directly or indirectly from claim 11, and therefore include all the limitations thereof, are allowable over the cited references.

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Accordingly, Applicant respectfully requests that the Examiner withdraw the rejections under 35 U.S.C. § 103(a) over Gross in view of Iddan, and allow claims 11-20.

In addition to the above, claim 14 further recites that the device comprises a ballast weight. In the Office action, the Examiner rejected the claim, stating simply that Gross inherently discloses a ballast weight without further detail. Applicant respectfully traverses the rejection. Applicant has found no express or inherent teaching in the Gross reference for a ballast weight. First, a text search of the reference reveals that neither word appears in the application.

Moreover, in view of the disclosure of the Gross reference, there would have been no need for a ballast weight. The Gross reference discloses an apparatus for drug administration, including an ingestible capsule. As stated in the abstract, the "capsule includes a drug, stored by the capsule. An environmentally-sensitive mechanism is adapted to change a state thereof responsive to a disposition of the capsule within a gastrointestinal tract of a subject. A driving mechanism, in response to a change of state of the environmentally-sensitive mechanism, is adapted to drive the drug directly through an endothelial layer of the gastrointestinal tract." Nothing in such a device inherently requires that there be a ballast weight.

In the Office Action, the Examiner rejected claim 35 under 35 U.S.C. § 103(a), as being unpatentable over Gross et al. (US Patent Application Publication No. 2004/0253304) in view of Iddan (US Patent Application Publication No. 2003/0214580) and further in view of Yokoi et al. (US Patent Application Publication No. 2003/0181788). Applicants traverse the rejection for at least the reasons that follow:

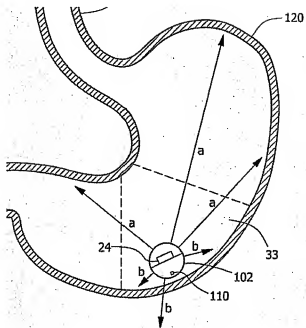
Claim 35 recites that "an imaging axis of said imaging device is aligned with the oblong axis of the detachable appendage when joined together." The claim has been amended to depend from claim 14, and therefore includes all the limitations thereof. The claim is allowable at least for the reasons discussed above with respect to claim 14 from which it depends.

New claim 47 has been added to further recite inventions of the present application. Claim 47, which depends from claim 14 further recites that the imaging device comprises the ballast weight to maintain a specific orientation of the spherical housing with respect to gravity. Support and further explanation of this amended claim may be found throughout the specification, including at paragraph [0041], which discloses:

[0041] An optional ballast or weight 110 (also shown in FIG. 3A) may be placed in the housing 102 to ensure that the imager 24, for example, may maintain a specific orientation with respect to gravity, for example, such that the viewing window may face upwards. . .

As discussed above with respect to claim 14, the Gross reference does not inherently disclose a ballast weight, nor does the reference disclose a ballast weight to maintain a specific orientation of the spherical housing with respect to gravity. Accordingly, claim 47 is allowable over the Gross and Iddan references.

New claim 48 has been added to further recite inventions of the present application. Claim 48, which depends from claim 14 further recites that the ballast weight is positioned in the spherical housing such that at least upon detachment from said detachable appendage, said imaging device is directed to image an area of the body lumen opposite a portion of said body lumen upon which the spherical housing is resting. Support for this claim may be found throughout the application, including at paragraph [0041] (quoted above) and Fig. 4, reproduced below:



Nothing in the cited references discloses or otherwise suggests the inventions of claim 48, including a ballast weight positioned in the spherical housing such that at least upon detachment from said detachable appendage, said imaging device is directed to image an area of the body lumen opposite a portion of said body lumen upon which the spherical housing is resting.

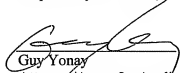
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In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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Dated: August 29, 2008

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